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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,697	11/16/2001	Robert Cosmo Di Luccio	14,853	2942

23556 7590 10/10/2003

KIMBERLY-CLARK WORLDWIDE, INC.
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EXAMINER

REICHLE, KARIN M

ART UNIT PAPER NUMBER

3761

DATE MAILED: 10/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/990,697

Applicant(s)

DI LUCCIO ET AL.

Examiner

Karin M. Reichle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 23-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 18 August 2003 is: a) ☐ approved b) ☒ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3-4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-13 and 23-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

3. The restriction requirement set forth in Paper No. 5 is still deemed proper and made FINAL.

Specification

Priority

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

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If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed application, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

5. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior

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application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Drawings

6. The drawings are objected to because Figure 1 and the description thereof on page 7, lines 10-12 are inconsistent, i.e. the Figure is partly cut away. Figure 2 and the description thereof on page 7, lines 13-14 are inconsistent, i.e. only part of the topsheet is shown. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

7. The drawings filed 8-18-03 have been received and placed in the application. Approval thereof is held in abeyance until the issues set forth in the preceding paragraph are resolved.

Description

8. The abstract of the disclosure is objected to because terminology which can be inferred, i.e. "The present invention relates to", "The present invention is also directed to", should be avoided. Correction is required. See MPEP § 608.01(b).

9. The disclosure is objected to because of the following informalities: 1) As discussed supra, the descriptions of Figures 1-2 and the Figures are inconsistent. 2) On page 10, the sentence on lines 27-29 is grammatically incorrect. 3) Page 15, lines 4-12 are incomplete.

Appropriate correction is required.

Claim Objections

10. Claims 14-22 are objected to because of the following informalities: in claims 14 and 16, "facing"(all) should be --faceable--. In claim 15, line 3, after "material", --is-- should be inserted. In claim 20, "further" should be deleted. Appropriate correction is required.

Claim Language Interpretation

11. With regard to claim 17, see page 4, lines 15-18 and page 5, lines 9-24 of the specification. "Medicaments" is interpreted in light of page 4, line 32- page 5, line 1, page 6, lines 24-28, and page 10, line 17-page 12, line 32. "Porous" is defined as set forth on page 6, line 34-page 7, line 2. "Effective amount" is defined as set forth on page 6, lines 13-17. "A pattern of a matrix of discrete segments" is interpreted in light of page 6, line 23-page 14, line 26 and page 16, line 24-page 17, line 6.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 14-16, 18 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayford '998.

With regard to claims 14, 15, 21 and 22, see claim interpretation section supra, the Figures, col. 1, lines 4-6, col. 3, lines 69 et seq, col. 4, lines 10-26, i.e. the topsheet is 2, the absorbent material is 1, the backsheet is 5, an effective amount is disclosed at col. 2, lines 64 et seq, a medicinal composition is 3, 4 and 6 or just 3 and 4 and disclosed at col. 2, lines 39-60, the discrete segments are 4, a pattern is disclosed at col. 4, lines 30-36, i.e. "a portion of", Figure 1 and 4, i.e. an array, and col. 2, lines 26-29, i.e. clusters, the volume is disclosed at col. 2, lines 17-25(the volume of a sphere is $\frac{4}{3}\pi(r^3)$), i.e. 3 picoliters to 400 nanoliters is equal to .000003-4 cubed mm and a capsule having a diameter of 200 microns has a volume of about .004 cubed mm.

With regard to claim 16, see Figure 1, the spheres 4 stick out of matrix 6 and the portions sticking out are "substantially" semi-spherical in cross section, see also col. 2, line 18.

With regard to claim 18, see again col. 4, lines 30-36, i.e. "a portion of" and col. 2, lines 26-29, i.e. clusters.

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With regard to claim 20, the composition is claimed as including a filler. However, the specifics of the filler have not been disclosed. Therefore, the composition as disclosed at col. 2, lines 39-60 is considered to include such a "filler".

102/103 Rejections

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claim 17 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hayford '998.

Claim 17 claims the frequency of positioning. See page 4, lines 15-18 and page 5, lines 9-24 of the specification. It is especially noted that as disclosed this is just the number of times an applicator "may" fire. Therefore this claim appears to be a product by process claim, i.e. the claiming of the frequency of possible firing of an applicator during the manufacture of the

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claimed product. This process does not appear to provide any further structure of the article than that already claimed. As set forth in MPEP 2113, it is the structure of the end product of the process which determines patentability not the process. Therefore, the Hayford device includes the same structure or obviously includes the same structure, as best understood.

Claim Rejections - 35 USC § 103

16. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayford '998 in view of Vega '209 and Krzysik PCT '500.

Applicant claims the discrete segments located in a specific pattern not taught by Hayford. Hayford only discloses application to a portion, e.g. clusters, an array, or the entire surface. However see Vega '209 at col. 29, lines 7-8 and col. 31, lines 19-32 and Krzysik at page 20, lines 19-29, i.e. interchangeability of a portion or the entire surface for the specific pattern as claimed. Therefore, to make the surface portion including segments 4 of Hayford the claimed specific pattern instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by Vega and Krzysik.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 14 -18 and 20-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 and 20-23 of copending Application No. 09/990,686(2003/0106605). Although the conflicting claims are not identical, they are not patentably distinct from each other because since the instant application has an effective filing date earlier than '686 but there was no administrative delay and Applicants could have avoided separate filings, the one way or In re Vogel test applies, i.e. are the claims of the instant application obvious in view of the claims of the '686 application. The answer is yes. With regard to claims 14-16, 18 and 21-22, see claims 12-17 and 20-23 of the '686 application and the definitions therein, e.g. what is considered a chemistry. Such claims teach substrates which are porous, chemistries, i.e. medicaments, chemistries which are discrete segments and provide skin separation, i.e. the substrate on which the chemistries are situated is a "topsheet", and an article which is absorbent and a diaper. While the absorbent material, backsheet, the position of the sheets and "an effective amount" are not explicitly claimed, it is well known in the absorbent article art that absorbent articles like diapers include a topsheet and a backsheet with an absorbent layer therebetween. Furthermore, it is well known to provide medicaments in amounts which provide the desired effect, i.e. the "effective amount". Thus to employ the layers and position them as claimed as well as an effective amount of the medicament chemistry on the device of the '686 claims would be obvious to one of ordinary skill in the art in view of the recognition that the layers and positioning thereof are well known in

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diapers and the desire of the '686 claims to include a diaper and obvious in view of the recognition that a certain amount of the chemistry is require to be effective and the desire of the '686 claims to provide an effect with the chemistry. With regard to claims 17 and 20, see discussion supra in paragraphs 14 and 15, which rationales are repeated here.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claim 19 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-17 and 20-23 of copending Application No. 09/990, 686(2003/01066605) in view of Vega '209 and Krzysik '500. See discussion in paragraph 16 supra and claim 18 of '686. Also note col. 30, lines 40-41 of Vega. Therefore to make the selective application, i.e. a portion, of the '686 claims the specific claimed pattern instead would be obvious to one of ordinary skill in the art in view of the interchangeability as taught by Vega and Krzysik.

This is a provisional obviousness-type double patenting rejection.

Common Ownership

20. Claims 14-22 directed to an invention not patentably distinct from claims 12-17 and 20-23 of commonly assigned 09/990,686(2003/01066605). Specifically, see the double patenting rejections supra.

21. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/990,686(2003/01066605), discussed above, would form the basis for a

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rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The prior art references teach other articles with medicaments thereon.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (703) 308-2617. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

K. M. Reichle
Karin M. Reichle
Primary Examiner
Art Unit 3761

KMR